

SIEMENS

ARCADIS Orbic

SP

Field Service Strategy

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Purpose of the Field Service Strategy

The Field Service Strategy is available on the Intranet.

The purpose of this document is to provide the technical service organization in the Regional Units with the necessary information to ensure optimum installation, startup and after-sales product support.

The information/support provided includes the following:

- Description of the major product characteristics
- Training concept for service personnel
- Special provisions during the product introduction phase
- Site planning and workflow for system startup
- Tools and auxiliary devices required for system installation, service and maintenance
- Meeting the time line and cost objectives
- Service concepts, e.g. Siemens Remote Services, etc.

The technical service managers will be informed when the Field Service Strategy is available.

The Field Service Strategy is available on the Siemens Med Intranet at:

CS/For Service/SP/Surgery/ARCADIS Orbic

Objective of the Field Service Strategy

The ARCADIS Orbic is foreseen to replace the SIREMOBIL ISO C-line.

ARCADIS Orbic is a mobile C-arm image intensifier unit with a new syngo® based image system and used for a variety of surgical applications including general, trauma, orthopedic, cardiac, neuro and emergency.

The 3D image reconstruction option represents a functional expansion of the existing ARCADIS Orbic. This upgrade will make it possible for surgeons to view 3-dimensional images (in addition to the usual 2-dimensional images) for intraoperative X-ray imaging. The application spectrum is restricted to the display of high-contrast objects such as skeletal structures.

The 3D Navigation interface option is an universal HW and SW interface which serves the navigation systems of different navigation companies. 3D Surgical navigation combines medical imaging with localization of surgical instruments during surgery. Simultaneous views of instruments in various planes and from any angles are possible. Surgical navigation systems enable surgeons to more accurately know the location of their instruments in relation to the patient's anatomy.

The calibration with the customer's navigation system generally requires the Siemens engineer and the engineer of the navigation company to be present at the same time. The navigation system itself is supplied by a navigation company and is handed over to the customer by the navigation company.

Development of the system was preceded by intensive market research to assure that not only the requirements of our customers but also those of our customer service organizations are met e. g. no laptop for service activities necessary, faster and auto-

mated 3D calibration procedure compared to SIREMOBIL Iso-C^{3D}, service friendly monitor trolley - full syngo service inside - SRS (Siemens remote services) capable.

Sales, economic and technical objectives through:

- Low life-cycle costs, from the standpoint of both the customer and the company.
- High system reliability, even during product initiation.
- Minimizing of service and maintenance costs.
- Value retention of the system.

ARCADIS Orbic System



Fig. 1

Definitions of Terms and Links

CB-DOC	Computer Based Documentation
CSE	Customer support Engineer
CS	Customer Services In a web-address CS stands for the CS web home page <u>http://cs.med.siemens.de</u>
USC	Uptime support Center
HSC	Headquarter Support Center <u>CS/For Service/HSC-TSC Support</u>
I.V.K.	Installed Volume Components
IPB	Installed Product Base
Field Service Strategy	Instructions for the R.U. regarding installation, startup and product service. This is equivalent to the terms "Product Info", "Service Instructions" or "Product Introduction Bulletin".
MCB	Service and Maintenance Cost Base
PG	Planning Guide <u>CS/For Service/Product Information/Planning/Planning Guides/SP Systems</u>
PM	Preismitteilung, price book
PMI	Planning-Installation-Startup Tool (installation time)
SPC/STC	Spare Parts Catalogue /Service Tool Catalogue <u>CS/For Service/Spare Parts Catalogue/Start SPC-STC/Special Products or CD ROM</u>
Technical Documentation	Product-specific Technical Documentation <u>CS/For Service/Product Information/SP Systems or CD ROM</u>

TC	Training Center; Course Offering
<i>syngo</i> ®	Common Software platform (synergy go). <i>syngo</i> ® is a registered trademark of Siemens AG
SRS	Siemens Remote Services <u>CS/For Service/Siemens Remote Services</u>
VS	Standard dispatch packaging
VH	Wooden dispatch packaging
VD	Sealed dispatch packaging
VQ	Quarantine dispatch packaging
SCD	Siemens Corporate Directory
ARTD	General Directive for Technical Service in the regional units

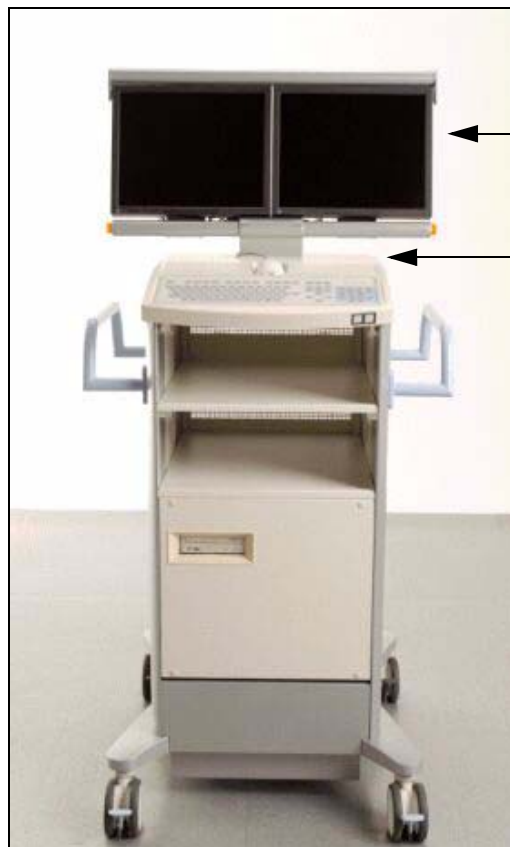
System Overview

Mobile C-arm



Fig. 1

Monitor Trolley



TFT Monitors

Remote connection &
Network connection

Fig. 2

System Characteristics

- *syngo*® based imaging system
- High connectivity with *syngo*®
- 1K² matrix, 30 f/s digital image chain
- 9 inch (23 cm) image intensifier
- Optimum workflow
- Increased generator output
- PC technology
- Flat screen monitors
- Siemens Remote Services (SRS)
- Proven *syngo*® service user interface (no laptop required)

System Part No.: 80 81 080

System Serial Nos.: 20001 to 29999

Options

- Subtraction / Roadmap
- DICOM standard
- DICOM advanced
- HIPAA
- 15 f/s (pulsed mode)
- Navi Link 2D
- High resolution monitors black and white 18"
- Printer low -end
- Printer high -end
- Laser light I.I.
- Laser single tank
- Diamantor chamber
- 3D image reconstruction
- 3D navigation interface
- Monitor interface for external live / reference monitors

Training

The responsible CSE must be promptly trained for the installation and servicing of the systems.

In addition to the technical training, good English language skills are indispensable, because training and technical documentation for ARCADIS Orbic is available in English only.

NOTE

Only appropriately trained service personnel may be entrusted with servicing of the system!

In accordance with the new training guidelines, the Training Center (CS TC) in Erlangen and also the Training Center in Cary will be offering a training program. Course dates and exact course descriptions will be published through the familiar channels. We would like to point out that during the system introduction phase course places will be assigned exclusively on the basis of the delivery list.

ARCADIS Orbic Training

Course	Course Designation	Course No.	Course Period
1	ARCADIS Systems	SP5ARCADB	5 days

ARCADIS Orbic is a syngo® based system. Therefore, visiting a syngo® course prior to the ARCADIS training is prerequisite.

The presently offered course is an upgrade on the knowledge of the SIREMOBIL Iso-C. Attending the course SP2SMCSMISO is prerequisite.

Equipment

During development of the ARCADIS Orbic a special effort was made to ensure that only service equipment introduced by CS need to be used.

NOTE

We would like to emphasize that only calibrated test equipment may be used. Technical Management in the field office is responsible for regular calibration.

All service equipment and aids can be found on the CD ROM and on the Intranet: CS/For Service/Spare Parts Catalogue/Start SPC-STC

Tools

For ARCADIS Orbic installation and service, the standard tools which are defined in the STC (Service Tools Catalogue) are required.

Only the exchange of the I.I., I.I. Optics or CCD Camera requires a special torque wrench (0.1 Nm - 0.8 Nm). This special tool is listed in the SPC/STC (Service Tools Catalogue).

Torque wrench Part No.: 80 79 241

Allen key socket BIT 1/4" 2.5mm (standard in CSE toolkit)

Spare Parts**NOTE**

Spare parts are published in the Spare Parts Catalogue (SPC) (see chapter "Quality Parts, Spare Parts Logistics and Returns").

The current data can be found on the CD ROM and on the Intranet:
CS/For Service/Spare Parts Catalogue/Start SPC-STC

Delivery of the System

The Regional Units are responsible for ensuring that the transport and storage requirements according to the PG are met.

In Germany, the system components are delivered by a contracted delivery service. In non-German countries, transport to the customer's location is handled by a local shipping company. The components are transported in standard packaging according to the following table (order-related variations are possible):

Direct delivery ex factory (all European countries) <i>Standard partial packaging</i>	Open packaging (TS), ARCADIS Orbic on a transport frame and pallet, all other components on pallets. Everything wrapped with special plastic film.
Standard sea or air freight	All components in wooden crates or boxes (VH).
Sea or air freight to countries with special quarantine regulations VD/VQ	All components in special wooden crates (VD/VQ). Also sealed in special plastic film (monsoon packaging).

Further detailed technical information (dimensions, weights, etc.) can be found in the "Planning Guide". The current version can be found on the Intranet on the Hyperwave Server under:

CS/For Service/Product Information/Planning/Planning Guides/SP Systems

It is an absolute prerequisite that every shipment takes the following guidelines into consideration:

- Air cushioned freight truck (all axles!).
- All system components are packaged so that the risk of transport damage is minimized.
- Upon delivery at the customer's location, the Project Manager or a product specialist assigned by him must be present!
The completeness of the shipment must be checked against the delivery documents.
In addition, the condition of the packaging must be examined.
- Any shortcomings must be communicated immediately in writing by the Project Manager to the responsible order processor in the logistics department.

The extent of services provided by the logistics company is determined on a country-to-country basis.

It is recommended that work steps be recorded by the Siemens Project Manager or by a person assigned by him.

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Planning, Room Preparation

The ARCADIS Orbic is designed to be installed and started up within the shortest possible period of time. Previous experience has shown that, with good planning and room preparation, installation can be achieved within **1 day** - from arrival on site to start of applications training.

To ensure problem-free completion of the entire system from planning to installation, a person responsible for the project or a Project Manager must be employed. The Project Managers assigned by the Regional Units are responsible for the site check, planning and project planning of the system.

The required technical information for the Regional Units is summarized in the "Planning Guide".

PG Manual	Print Number: SPR2-320.891.01.01...
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The current version of the "Planning Guide" can be found on the Intranet:
CS/For Service/Product Information/Planning/Planning Guides/SP Systems.

Support from the factory

Site checks, drafting of planning recommendations and execution plans shall be performed on request by MED ES PM (Project Planning, Engineering).

The required technical, project-specific documents shall be made available by the field office promptly.

All services provided by MED ES PM shall be billed to the field office on a time basis. The current MED ES PM prices are applicable.

Startup

ARCADIS Orbic systems are configured and tested at the factory using the proven pre-staging method. Refer to the installation time catalogue for the time required for startup and adjustments done in the field.

In Germany, bringing the system into the room and start-up are performed by a subcontractor (shipping company). The employees of the authorized subcontractor have been trained in the proper performance of the work steps that must be done on ARCADIS Orbic systems.

Logistics (MED SP SCM) coordinates Installation and startup. Prior to shipping the system, the checklist from MED SP SCM has been filled out with the customer-specific data and sent back to MED SP SCM.

The Acceptance Test and also if network configuration is required this work must be completed by the responsible Siemens department.

In non-German countries, installation must be performed by trained personnel from the Regional Unit.

The complete handing over time can vary due to country-specific regulations (such as in Germany, the acceptance test according to RÖV) and also depending on whether network configuration is necessary. Customer training and any resulting changes to the standard programming are not included in the time allowance indicated.

ARCADIS Orbic

- Unpacking and start-up time (incl. image quality test): ~ 6 hours
- Acceptance Test: ~ 2 hours (Siemens employee)
- Network configuration (optional): ~ 1 hour (Siemens employee)

Also refer to the PMI tool on the Intranet:

[CS/For Service/Product Information/Planning/PMI/SP systems.](#)

The system is shipped from the factory so that only a function check, an adaptation of the film/screen combination (Option) and a final image quality test needs to be performed.

Reporting and Documentation

The supplied report "Installation and Start-up ARCADIS Orbic" must be completed and signed by the responsible PM.

A copy of the report must be sent by mail or fax to the following address:

**SPQPI
Henkestr. 127
D-91052 Erlangen
Fax +49 9131 84 8750**

The system and site locations must be entered in the existing data management systems on the basis of the IVK list by the responsible persons in the region/local Siemens company.

The Technical Managers in the Regional Unit must ensure that each installation is recorded using the allowable maintenance units in their data management systems.

Particularly during product introduction, but also later for evaluation of system quality, the analysis and reporting of field data is a critical contribution to the maintenance and improvement of product quality. Determination of the installed volume is thus given a very special significance.

The procedure regarding "Documentation of the Installation" is specified in the ARTD - 001.709.02.

After completing an ARCADIS Orbic installation, each field office must record all product and customer data in SAP.

Application

A 1 day application training course is recommended for the syngo® based ARCADIS Orbic system for the customers with no experience with syngo®.

For the ARCADIS Orbic 3D a two day application training course is recommended.

6 - 4 Planning, Startup, Reporting and Application

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Service Concept

With ARCADIS Orbic, repair and troubleshooting is confined to the board or component level. The replacement of parts is limited to the FRUs listed in the Spare Parts Catalogue.

The goal of this service concept is to find an optimum between the spare part price and the uptime of the system for the customer.

Service Software

The service software is based on syngo® service and integrated into the imaging system PC.

It provides the full service support (without laptop) via the service user interface, and is also used for other modalities.

To access the service SW, a licence key has to be generated and typed into the system. These license keys are time-limited and protect the service SW against unauthorized use.

The license keys for the syngo® based Image system are assigned normally by the USC or by the CS HSC 1 if no USC is available.

For more Information about the licensing procedure see ARTD - 001.719.12.02.01

The following service level is available:

Level 3	Basic, Inhouse
Level 5	Expert, Experienced Inhouse
Level 7	Siemens, for Siemens personal only (not be to sold)

NOTE

The ARCADIS Orbic software including the service SW is the property of Siemens Medical Systems and may not be given to third parties.
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Modifications and Safety Updates

To increase reliability, performance and safety, modification orders in the form of updates (UIs) and Service Instructions (SIs) are published and can be found on the Intranet:

(CS/For Service/Product Information/SP/Updates-Modifications SP)

All UIs and SIs must be performed within the specified timeframe to assure the best possible system performance.

A detailed process description that is mandatory for the Regional Unit, including cost data and responsibilities, can be found in the ARTD - 001.714.01.05.01.

Deficiencies and Customer Complaints

Every employee is required and obligated by C-MQR 4.14/01 to report quality and safety deficiencies to the factory using the complaint form.

These complaints are subject to strict guidelines as regards processing and are evaluated and followed up by teams that have been specially created for this purpose in the factory.

Siemens Remote Service (SRS)

SRS for the ARCADIS Orbic is possible.

For information about SRS see the following link:

<http://cs.med.siemens.de/SRSToolkit/english/cse.htm> and button.

Under this link you find also the following document: Installation of Siemens Remote Services (SRS) SP00-000.816.02..

Remote Service

Remote service is an important part of the service maintenance program, therefore it is absolutely necessary to connect as many as possible ARCADIS sites to remote service. The goal is to have at least 50% of ARCADIS Orbic systems connected to Siemens Remote Services.

Customer Services in cooperation with the business divisions has decided to establish a new concept for Siemens Remote Services (SRS). This concept defines the following principles:

- Router connection: a single data transmission line connects one or more systems.
- Pre-configured routers are available (independent of the specific system).
- The local Project Manager has to order the router components. He has to supply the data for the final configuration (see Router Checklist).
- The final configuration is performed by the central provider (see Checklist) or your local USC, depending on who will perform the final configuration.

Thus the router connection has to be used, as this provides the maximum in data security. Particularly if a review station is installed at the customer site, there is only one remote access to maintain both devices. Also when other modalities such as MR, CT or other AX systems are located nearby at the customer's site, the router is the only choice for remote connection.

Three different packages for final configuration are available:

- Standard: SRS router is already installed, a new system is simply added to the network and to the SRS server.
- Extended: a new pre-configured SRS router should be installed.
- Advanced: A customer administered router is planned for use with SRS.

For more details, contact the UPTIME Services@med.siemens.de, or see the Siemens Remote Services Planning Guide on the SIEMENS Intranet.

NOTE

The local Project Manager has to plan and coordinate to assure that a telephone connection (ISDN, analog or VPN) or access to an existing router is available during system start-up as well a connection to the network.

NOTE

Siemens Remote Services (SRS) is essential for the service business.

NOTE

A Modem SRS connection is not supported by the ARCADIS Orbic system.

Quality Parts

Q parts are specially labelled spare parts that must be returned to the factory as soon as possible for investigation of the failure regardless of other regulations such as value limits or disposal guidelines.

Prioritization is specified as required by the quality specialists in the particular business division. Classification is dynamic, i.e. the status "Q Part" can be set or deleted several times during the product life cycle. These parts are designated in the SAP data system (Q code).

For the ARCADIS Orbic, components were defined as Q parts.

The goal is to avoid unnecessary high warranty costs and a significant improvement in product quality during the product introduction by means of quick detection of deficiencies.

The prerequisite for this is that:

- the part to be returned is accompanied by a detailed error description.
- the parts are returned to the factory (CS ML) immediately,

These are parts that must be returned to the responsible departments in the factory for quick investigation of the error.

Spare Parts Logistics

General Remark

The parts defined as spare parts are listed in the Spare Parts Catalogue on the Intranet: **CS/For Service/Spare Parts Catalogue/Start SPC-STC/Special Products.**

CD ROMs are distributed automatically based on the distribution list maintained by CS SP.

Spare parts are continuously updated to the requirements of the service organization based on needs orientation, replaceability and time optimization.

Spare parts are processed according to the rules defined by CS ML.

Shipment is made from the locations in Germany (Frankfurt), USA (Memphis) and the Asian Express Center, Singapore.

Returns Processing

Parts that can be or must be returned should be returned immediately to the responsible return parts department in Erlangen.

For Complaint/Q parts the work instructions of Technical Service or the Med Quality Guidelines are applicable:

Complaint handling the ARTD - 001.713.02..

Q Parts the ARTD - 001.713.01..

The principles for economical processing are specified in ARTD - 001.715.01.03..

The particular agreements made between Med CS ML and the Regional Units apply for logistic processing of the spare parts cycle.

Spare parts must always be returned with the returns form. In a warranty situation, stating this fact on the returns form is mandatory.

Maintenance

Current maintenance data are published on the Intranet under "MCB".

Installed Volume Components

The company headquarters and all Regional Units together must satisfy a variety of functions that relate to an exact knowledge of the installed products/components and their configuration.

These are essentially

- legal aspects (product liability, warranty, updates, etc.)
- administrative aspects (service administration, billing, etc.)
- qualitative aspects (reporting, reliability, etc.)

All regional units must compile an "installed volume" file for products that are in operation in that particular country so that they are able to satisfy all required functions. To do this, a worldwide effort is being made and monitored by all business divisions on an equal basis to determine which products/components need to be recorded in this file.

Since the information about the installed products/components can also be used to monitor safety updates, it is important that the components are recorded correctly and completely in the "installed volume".

Through access to the data for the "installed volume" and data on the handling of malfunctions, all required information about the period of a malfunction, spare parts used and, from some countries, even an exact description of the malfunction event, is now available electronically.

Service Contract

A service contract ensures uptime, response time, reliability and image quality commitments. Other benefits for the customer of having a service contract are the ability to tailor the contract to individual needs and / or cover consumables. For ARCADIS Orbic an Evolve package is available. The Evolve Package is a component of a service contract. The portfolio of contractual offers ranges from Performance over Shared to software license contracts.

Further support is available through CSM, Customer Services Marketing or can be found on the Services Marketing Intranet page.

Link: [CS.med.siemens.de](https://cs.med.siemens.de) under "For Sales & Marketing", "Service Marketing Support".

NOTE

The service software is the unrestricted property of Medical Solutions and must not be made available to third parties.
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Service Escalation

Service must be performed in accordance with the processes described in the Service Escalation Strategy.

CS Knowledge Base

The knowledge base contains known service scenarios and their solutions as well as error descriptions and speed infos. Every CSE can contribute to building up the knowledge base by entering a suggestion.

The CS knowledge base is published on the Intranet under <http://www-cs.med.siemens.de/sharenet>

KB is accessible from SRS connected systems as well.

Technical Documentation

Document structure

The technical documentation is available in English with the following exceptions:

• Unpacking Instructions	German/English
• Startup Instructions	German/English
• Maintenance Instructions	German/English
• Planning Guide	German/English
• Maintenance Plan	German/English/Spanish/French

The **product-accompanying information** is available in a hardcopy version (paper) and is comprised of:

- the *Technical Documents*. This binder is used to file the Installation Instructions and wiring diagrams for the complete system and its options
- the *Operating Instructions*.

Maintenance is the customer's responsibility.

The **non product-accompanying information** (*CB-DOC*) is available as online documentation on CD ROM, and the newest version is always available on the Intranet.

The *CD ROM (CB-DOC)* is distributed to a list of CSEs. The distribution list is generated on the basis of the Socrates Training Information System and the "Siemens Corporate Directory" (SCD), but can also be maintained by Technical Management in the field offices. Updates to the CD ROMs are also made according to the distribution list at regular intervals.

The latest version of the CB-DOC is available on the Intranet.

Hardware requirements for CB-DOC

To read the technical documentation that does not accompany the product (CB-DOC), a laptop complying with the requirements specified in ARTD is necessary.

Important information regarding data security

NOTICE

Technical Management in the Regional Unit is responsible for making sure that both current as well as old documents on CD-ROM do not fall into the hands of third parties, and that once a technician terminates employment with the Siemens Corporation, such documents are returned.

Safety Information

All activities related to installation and repair must be performed in accordance with the relevant applicable technical documentation.

When performing work and tests, the safety information contained in the technical documentation must be observed.

Additional regulations are published in ARTD Part 2, Chapter 1.

To the extent necessary, the relevant safety information for the particular work steps is stated again in the individual chapters in the technical documentation.

For room planning, startup and customer service work the relevant national regulations must be complied with.

X-Ray Ordinance (Röntgenverordnung §16) applicable only in Germany

- With new installations, all systems have been pretested in the factory; only supplementary checks need to be performed.
- Following all customer service work that may affect image quality, a partial acceptance test must be performed, e.g.
 - Replacement of image-producing components (X-ray tube unit, image intensifier, camera, collimator on the tube unit).

Disposal

Where parts cannot be returned to the factory, they must be recycled or disposed of in accordance with the relevant legal regulations. The applicable instructions can be found in the technical document entitled "Disposal Instructions".

11 - 2 Safety Information, Regulations and Disposal

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